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FDA Media Call Unapproved "chelation" products Moderator: Siobhan DeLancey October 14, 2010 1:00 pm EST

Coordinator:

Welcome and thank you all for standing by. At this time all participants are on a listen only mode. During the question and answer session please press star 1 on your touchtone phone to ask a question. Today's conference is being recorded. If you have any objections you may disconnect at this time.

And now I'd like to turn the call over to Siobhan DeLancey. Thank you. You may begin.

Siobhan DeLancey: Thank you for very much. This is Siobhan DeLancey from the FDA

Office of Public Affairs. This is an FDA teleconference for press to get more
information about an FDA announcement about unapproved chelation
products. This briefing is for credentialed media only.

Our speakers today are Michael Levy, Director of the Division of New Drugs and Labeling Compliance in the Center for Drug Evaluation and Research at FDA, and Dr. Charles Lee, a medical officer in the same division.

We also have technical experts standing by to answer your questions - Dr. Alberto Gutierrez, Director of the Office of In Vitro Diagnostics at the Center

for Devices and Radiological Health here at FDA, Gary Coody, FDA's National Health Fraud Coordinator. Elizabeth Miller and Raichell Brown are both pharmacists in the Internet and Health Fraud team at the Center for Dri-I'm sorry, the Center for Drug Evaluation and Research.

Our speakers will make brief remarks and then we'll open up the call for questions from the media. When asking a question, please state your name and affiliation and please limit yourself to one question and one follow up so that we can get to as many questions as possible.

The news release for this announcement has been sent to reporters on our media list as well as posted to FDA's Web site at fda.gov under public health focus and the warning letters are also posted online.

I'll now turn the call over to Mr. Levy.

Michael Levy:

Thank you Siobhan. Today the FDA's advising consumers to avoid so-called chelation products sold over the counter because these products are illegally marketed and can be dangerous to health.

Chelation involves the use of chemicals to bind and remove metals from the body. All FDA approved chelation products require a prescription because they can only be used safely under the supervision of a health care practitioner.

FDA has never approved any chelation product for OTCs for any health condition. FDA today issued warning letters to eight companies marketing unapproved OTC chelation products. Although some of these products are marketed as dietary supplements, they are in fact, unapproved drugs.

These companies falsely claim that their product treat a variety of ailments including autism and cardiovascular diseases. Some of the companies also claim to treat Parkinson's Disease, Alzheimer's Disease, macular degeneration and other serious conditions.

The product subject to the warning letters issued today come in various dosage forms including transmucosal sprays, suppositories and clay baths. In addition, some of these companies market unapproved screening tests that claim to detect the presence of heavy metals in urine to falsely justify the need for chelation therapy.

FDA's concerned that unapproved OTC chelation products are dangerously misleading because they target patients and caregivers of patients that have serious conditions with limited treatment options. Also, these products pose serious safety issues which our medical office, Dr. Lee, will address. Dr. Lee.

Dr. Charles Lee: Thank you. As Mike Levy mentioned, chelation can be dangerous and can cause serious harm particularly when not performed under the close supervision of a licensed health care practitioner. Chelation can result in serious side effects such as dehydration, kidney failure and even death.

> FDA's concerned and consumers are administering chelation products to children and to themselves without the proper supervision of a health care practitioner.

FDA's also concerned that patients with serious conditions, such as cardiovascular diseases, will delay seeking proven sometimes essential medical care when relying on unproven OTC chelation products.

FDA advises patients that have unapproved OTC chelation products not to use them. People should contact their health care professionals if they are taking such products and experience adverse events. FDA encourages consumers, caregivers and health care professionals to report adverse events related to use of these products to the med- FDA's Med Watch Safety Information and Adverse Event Reporting Program and www.fda.gov/medwatch/report.htm or by phone at 800-FDA-1088 or 800-322-1088.

Siobhan DeLancey: Thanks Dr. Lee and right now we'd like to take questions from credentialed media. And conference coordinator, do we have anybody with questions from the media?

Coordinator: We do. One moment please. Again, as a reminder, if you do have question, please press star 1 and record your name when prompted.

Our first question comes from (Saundra Young). Ma'am, your line is open.

(Saundra Young): Yes hi. Thanks for taking my call. You see advertisements for these products on blogs, particularly autism blogs, all the time. And I'm just wondering, do you know, have any idea, how many kids are being exposed to these products?

Michael Levy: No, we don't have numbers on that.

Siobhan DeLancey: That was Mike Levy. (Saundra), do you have a follow up?

(Saundra Young): Yes. Could you kind of explain to us how these products, what these products do in the body that's so damaging?

((Crosstalk))

(Saundra Young): It causes kidney failure and dehydration.

Michael Levy: I'm going to ask Dr. Lee to respond to that.

Dr. Charles Lee: Right. Sometimes some of the chelation productions themselves can cause actual damage to the kidney the liver. In addition, in circumstances where there may be heavy metal intoxication in the actual chelation of the - of whatever that heavy metal is can actually, can actually cause kidney damage.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our next question comes from Malcolm Spicer. Your line is open. Please state your affiliation.

Malcolm Spicer: Thank you. I'm with Elsevier Business Intelligence. My question is, one, dodid any of these companies apply for OTC status for their product that is now being warned about? And two, what was it that prompted FDA's enforcement here? Were there reports to the agency about children or other patients having adverse affects or was it simply ongoing monitoring of ads and so on? Thank you.

Michael Levy: So, the first question again. Could you just repeat the first question?

Malcolm Spicer: Yes, my question was whether any of the companies that had been warned in these - in this announcement actually applied for - to have an approved drug - OTC drug - for chelation.

Michael Levy: The answer's no. And again, there are no FDA approved over the counter treatments - chelation treatments. And the second question, in terms of what prompted this investigation, obviously we can't comment on our - what

initiated the investigation but I will say that, you know, we have noted an increase in the availability and prominence of these products on the Internet.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: We have a question from (Trine Tsouderis). Your line is open. Please state

your affiliation.

(Trine Tsouderis): Hi. I'm with the Chicago Tribune and I'm wondering about the heavy metal screening tests. I'm wondering if someone could talk a little bit more about what - are these provoked, you know, provoked urine tests or - and what exactly is illegal about them?

Siobhan DeLancey: I'm going to ask Alberto Gutierrez from CDRH to address that. Go ahead.

Dr. Alberto Gutierrez: Is this mike open?

Siobhan DeLancey: Yes.

Dr. Alberto Gutierrez: Yes, the old medical devices, such as the over the counter screening tests that are (part) medical devices, and as such, require either a clearance or approved by the FDA and we're not aware of any tests that have been clear or approved for this type of use.

Siobhan DeLancey: (Trine), do you have a follow up?

(Trine Tsouderis): Yes, so is that right that there are no over the - there's no sort of over-the-counter heavy metal screening tests that have been approved by the FDA. Is that what you're saying?

Dr. Alberto Gutierrez: That's correct.

(Trine Tsouderis): Okay. All right. Oh, that's good to know. And also have there been any deaths associated with EDTA - sodium I- EDTA?

Dr. Charles Lee: There was one death that we're aware of associated with use of intravenous EDTA in a child with autism. But we'd also point out, you know, in general that we know that there are safety risks with chelation products as a group. We're not aware of other adverse events, reports for these specific products.

However, adverse events would be very much underreported for these products. The companies really have no incentive to submit our reports and certainly there's a lot of underreporting in over the counter settings anyway. So the fact that we don't have evidence of a lot of adverse events does not mean necessarily that there's not any health risk from them.

Siobhan DeLancey: And that was Dr. Charles Lee. Thank you. Next question please.

Coordinator: Our next question comes from April Fulton. Your line is open. Please state your affiliation.

April Fulton: Hi. I'm with NPR. So I was wondering are these companies that got the warning letters today just indicative of the kinds of things you've been seeing? You said that you've seen a trend of more and more of these products being sold.

Michael Levy: I think that the products - that were represented warning letters today represent the wide variety of products that are available over the counter to consumers now.

Siobhan DeLancey: April, do you have a follow up?

April Fulton: No, it already got asked. Thank you.

Siobhan DeLancey: Okay thank you. Next question.

Coordinator: Our next question comes from Daniel DeNoon. Your line is open. Please state

your affiliation.

Daniel DeNoon: Thank you. I'm with Web MD. These - chelation products are used - perhaps

FDA approved products for all I know - are used very frequently to treat

children with autism.

What's the FDA's view of this? Does today's action indicate any - an

increased concern over the use of these products in autism treatment by I

would guess physicians?

Michael Levy: Well, let me take the first part of that and then I'll turn it over to Charlie. But

the products that we are acting against today are all offered over the counter to

consumers where all of the FDA approved drugs are - require a prescription

and require the intervention of a health care practitioner. And I'll just turn it

over to Charlie if he has anything to add.

Dr. Charles Lee: I mean, certainly off label use of appr- FDA approved products would come

under kind of the - under the - so to speak, the practice of medicine. Again, as

Mike mentioned, we're concerned about over the counter use. Certainly the

risks of using the approved products undoubtedly would be similar if you used

it for autism as it would be for the actual approved indications. And all of

those products are prescription and to be used under phys- supervision of the

physician.

So I would point out that these interventions actually perhaps though the American Academy of Pediatrics is that - has actually suggested that none of these interventions actually could be endorsed for treatment for autistic spectrum disorders outside of the well designed and appropriate cl- monitored clinical trial.

Siobhan DeLancey: Thank you Daniel. Do you have a follow up question?

Daniel DeNoon: Just wanted to clarify. So the FDA is not then considering any further action

against the off label use of approved chelation products?

Dr. Charles Lee: This action really deals with the use of the over the counter products.

Daniel DeNoon: Thank you very much.

Michael Levy: Just - one further note on that. I just want to reiterate that there are no - that

none of the chelation products are approved for autism, meaning that we do

not have evidence right now that they are safe and effective for that use.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: We have a question from Kristina Fiore. Your line is open. Please state your

affiliation.

Kristina Fiore: Hi. I'm with MedPage Today but my question was answered. Thanks.

Siobhan DeLancey: Okay thank you. Next question please.

Coordinator: Melissa Healy. Your line is open. Please state your affiliation.

Melissa Healy:

Yes, I'm with the Los Angeles Times. You mentioned that a couple of the - of these products were being marketed as dietary supplements. And I wonder if you could address the question of whether - effectively what - on what basis they might have been considered dietary supplements and whether your concern is simply that as dietary supplements, they're simply useless or are they actually dangerous?

In other words, are they effective at doing something that could be dangerous to consumers?

Michael Levy:

Well, as I said in the opening statement, although some of these products are marketing as dietary supplements, because of the conditions for which they're offered, we consider them to be drugs. And in order for a drug to be marketed in the U.S., it needs to be proven safe and effective before it goes to market. These products do not have proven safety and efficacy.

Melissa Healy:

So it's largely on the basis of their claims to treat that they are considered to be drugs. Not on any of their content.

Michael Levy:

You know, we're not going to say today or we're not going to describe to firms how any of these products might be legally marketed. What we're telling consumers today is that any chelation therapy that's marketed over the counter is suspect.

Siobhan DeLancey: Thank you. Next question please.

Coordinator:

I have a question from Elizabeth Mechcatie. Your line is open. Please state your affiliation.

Elizabeth Mechcatie: Hello. I'm from Internal Medicine News and Family Practice News. So there - other then the one death you're aware of, are there any other adverse events that have been reported to the FDA or in the medical literature that you're aware of associated with these products?

Dr. Charles Lee: As I mentioned, we're not aware of other adverse reports with the specific products in this action or this class products use in this way. But again, as I mentioned before, the lack of events - adverse event reports - doesn't really give us comfort that - or the ability to include that they're not associated with them because again as I also had mentioned before, companies are - really have no incentive to submit reports. Consumers may not consider making reports because of the labeling and so - and in addition and finally, underreporting is common in all adverse event reporting and particularly for over the counter products.

Elizabeth Mechcatie: Yes. Thank you.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: We have a question from (David Bellion). Your line is open. Please state your affiliation.

(David Bellion): Hi. I'm with FDA News. I was hoping you could maybe give a sense of how the big the market for the approved chelation products is in terms of how many have been approved by the FDA and what some of those are.

Dr. Charles Lee: Yes we have - there are - again for - these are for conditions of generally heavy metal intoxication. There's a product, (dymer caprol), is an approved product, for arsenic gold and mercury poisoning. Calcium - dy- excuse me, for lead poising. Calcium sodium NDTA also for lead. (Soximer) DMSA is also

an approved product. And (penicillimean) which is also approved by copper intoxication in Wilson's Disease.

Siobhan DeLancey: Thank you. Do you have a follow up?

(David Bellion): No, that's fine. Thank you.

Siobhan DeLancey: Okay thank you. Next question please.

Coordinator: And a question from (Mariam Solko). Your line is open. Please state your

affiliation.

(Mariam Solko): Hi. First of all, thank you for clarifying. I thought suddenly breaking news that

chelation was approved for treating autism because I thought that wasn't the

case. But you mentioned that the companies have no incentive to report

adverse events. Are doctors reporting any of these or do you think parents are

telling the doctors what they gave their children.

Dr. Charles Lee: I mean, that's certainly a possibility and then a lot of these are labeled in such

a way to imply that they're not associated with adverse events so we - if

something happens somewhere down the line, maybe not - you need a few

minutes after getting a product - but maybe the next day, parents may not

make the association between the two.

(Mariam Solko): So then how - I guess that would be the further explanation then is how long

would it take for you to actually get sick from a product like this?

Dr. Charles Lee: I would - I mean obviously we would - it would really depend on what kind of

problem came from it. So...

(Mariam Solko): Okay then I...

Dr. Charles Lee: I mean, certainly like an immediate hypersensitivity reaction might be something that would occur within minutes but it may take, you know, days to weeks for somebody to have a problem, say, from kidney failure, something

like that.

(Mariam Solko): Okay.

Siobhan DeLancey: Thank you.

(Mariam Solko): No, I have a follow up if you don't mind.

Siobhan DeLancey: Okay.

(Mariam Solko): What about just for further explanation because I'm trying to figure out what the take home message is for folks who may not normally be using these products. When would you normally be prescribed with chelation therapy? What's the normal reason for getting this and how to do you get the lead poisoning or the other poisons you mentioned?

Dr. Charles Lee: That's a good question. I mean, lead poisoning actually is a very good example in children. Chelators are approved for treatment of lead poisoning in children that may get it from eating paint chips or exposed to lead in dust, that type of thing, in homes from paint. Chelation therapy is approved for treatment of iron intoxication. I did mention the drug, (deperoximine), which is approved - an approved product for treatment of iron intoxication.

Again, basically these are conditions associated with toxicity from various heavy metal poisoning and the source of the poisoning would vary depending how - what the heavy metal would be obviously.

Siobhan DeLancey: Thank you. And I think we've got just time for two more questions.

Coordinator: We have a question from Rebecca Voelker. Please state your affiliation.

Rebecca Voelker: Yes, I'm with the JAMA News Section. And I'm wondering if you could identify what the actual compounds are that cause harm in the over the counter products and how they differ from the actual active ingredient in the prescription product.

Michael Levy: Well, you know, I don't think we know what the exact composition of all these products are. We mainly know what they're being marketed for and that they're being marketed as chelation therapy. And again, I would emphasis that one of the things that we're trying to get consumers to take home from this action today is that these products are not meant to be marketed over the counter at all and that the only FDA approved drugs that are available are available by prescription and with the help of their health care practitioner.

Siobhan DeLancey: Thank you. Do you have a follow up?

Rebecca Voelker: Yes, I'm wondering if you recommend whether physicians should start asking their patients specifically if they're using these over the counter products.

Dr. Charles Lee: That would be a good thing for physicians or other pra- health care practitioners.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: Our final question comes from Trine Tsouderis. Your line is open. Please state

your affiliation.

(Trine Tsouderis): Hi, it's Trine again with the Chicago Tribune. I'm wondering if - and I -

maybe you don't know. I think it's - I just - you just answered a question that

makes me think that you don't - but do you know if most of these products are

claiming to have sodium, EDTA or di- or calcium (disodium) EDTA? And is

there a difference between the two and d-, you know, especially in terms of

toxicity or warnings or whatever, so?

Michael Levy: Again it's Mike. I'll mention - I'm not sure we know exactly what's in some

of these products. Actually there is a difference between calcium and sodium -

calcium (disodium) and sodium EDTA. And in fact, the death was associated

with use of the sodium EDTA not the calcium (disodium) EDTA.

(Trine Tsouderis): Okay.

Siobhan DeLancey: And I think Raichell Brown, one of our pharmacists is going to add to that.

(Raichell Brown): A number of the products who received warning letters today do list EDTA as

an ingredient. And one thing that they do is they use EDTA loosely. They

don't distinguish whether or not it is (disodium) EDTA or (disodium) calcium

EDTA. And as Dr. Lee said, there is a difference. There's a difference in the

toxicities of each product. But both of them do have some types of

(unintelligible) that shouldn't be used over the counter.\

Siobhan DeLancey: And (Trine), do you have a follow up?

(Trine Tsouderis): Also yes, just a last follow up. What can be done to - you know, what are the actions if these guys don't do anything about their product or don't respond?

What does the FDA - what kind of action can you take?

Michael Levy: Well, FDA has a variety of enforcement mechanisms at their disposal including seizure, injunction and possible criminal sanctions for firms that don't comply with warning letters.

(Trine Tsouderis): Okay.

Siobhan DeLancey: Okay thank you folks. This concludes our media teleconference for today.

And thank you for your participation. We'll have a reply up in about an hour.

And it'll be available for the next seven days.

If you have follow up questions, please contact me, Siobhan DeLancey, at 301-796-4668. Thank you and good bye.

Coordinator: That does conclude today's conference. Pl- thank you for par- your participation. You may disconnect at this time.

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